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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/049,227	03/27/98	REDMON M	4821-304

HM12/0705

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EXAMINER	
DELACROIX MUIRHEI,C	
ART UNIT	**PAPER NUMBER**
1614	20

DATE MAILED: 07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/049,227	REDMON et al.
Examiner	**Art Unit**
Cybille Delacroix-Muirheid	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 19, 2001*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-37* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

The following is responsive to Applicant's amendment received Apr. 19, 2001.

Claim 38 is cancelled. No new claims are added. Claims 1-37 are currently pending.

The previous rejection of claim 22 under 35 USC 112, paragraph 2, set forth in paragraphs 1-2 of the office action mailed Nov. 2, 2000 is withdrawn in view of Applicant's amendment and the remarks contained therein.

The previous rejection of claims 23-25 under 35 USC 102(e), set forth in paragraph 4 of the office action mailed Nov. 2, 2000 is withdrawn in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing (1) the previous claims rejection under 35 USC 102(b) with respect to claims 21, 29; (2) the claims rejection under 35 USC 103(a); and (3) the claims rejection under 35 USC 112, paragraph 2 have been considered but are not to be persuasive.

Claims rejection under 35 USC 102(e)(claims 21, 29):

Applicant argues that the compositions are not anticipated by El-Rashidy because El-Rashidy does not disclose each and every element of the claims composition. Specifically, Applicant argues that the preferred composition taught by El-Rashidy does not specifically teach pregelatinized starch.

However, the Examiner refers Applicant to col. 3, lines 43-44 where pregelatinized starch is disclosed as a suitable disintegrant. The Examiner submits, therefore, that compositions containing pregelatinized starch is readily envisaged by one of ordinary skill in the art.

The rejection is maintained.

Claims Rejections under 35 USC 103(a):

Applicant essentially argues that the prior art fails to disclose or fairly suggest pharmaceutical compositions containing optically pure enantiomer of fluoxetine. In fact, Applicant argues that the prior art (PDR) provides a disincentive to prepare compositions that contain optically pure fluoxetine. Applicant

additionally argues that the prior art does not teach the desirability of fluoxetine compositions that are free of lactose nor does the prior art disclose compositions with the claimed DISSOLUTION rates. Applicant states that El-Rashidy suggests racemic fluoxetine tablets that dissolve in greater than 3 minutes but there is no indication that the tablets are lactose free. EPA '281 may not teach preferred tablet compositions containing lactose; however, EPA '281 does list lactose as an excipient. Additionally, the prior art fails to disclose or suggest the desirability of anhydrous compositions. El-Rashidy does not take precautions to prevent water from getting into the fabrication process as evidenced by the presence of dicalcium phosphate dihydrate. EPA '281 fails to teach the desirability of anhydrous compositions. Finally, Applicant argues that El-Rashidy discloses a laundry list of disintegrants but fails to disclose compositions containing two disintegrants such as pregelatinized starch and microcrystalline cellulose.

Said arguments have been considered but are not found to be persuasive.

With respect to Applicant's arguments concerning the use of optically pure fluoxetine, the patent to El-Rashidy discloses compositions containing racemic fluoxetine. The Examiner maintains that El-Rashidy in view of PDR intimates that either one of the enantiomers may be used therapeutically. Furthermore, isomers of a racemic compound are expected to have differing activities; one isomer is expected to more active than others (optically active isomer substitution was held to be obvious). See In re Anthony, 162 USPQ 594; In re Adamson, 125 USPQ 233. Absent evidence to the contrary, modification of El-Rashidy to specifically use optically pure fluoxetine would have been obvious to one of ordinary skill in the art because the PDR suggests that the isomers of racemic fluoxetine would be therapeutically effective. One of ordinary skill in the art would reasonably expect optically pure fluoxetine to be effective in treating patients. Please note that "expected beneficial results are evidence of obviousness, just as unexpected beneficial results are evidence of unobviousness." In re Novak, 16 USPQ 2d 2041 (Fed. Cir., 1989).

In addressing Applicant's arguments that the prior art fails to teach the desirability of lactose free fluoxetine containing compositions, Applicant is respectfully reminded that the preferred compositions

disclosed by El-Rashidy and EPA '281 do not contain any lactose. Furthermore, with respect to the claimed compositions that require microcrystalline cellulose and pregelatinized starch, such a modification would have been obvious in view of El-Rashidy which discloses the use of microcrystalline cellulose and pregelatinized starch as suitable disintegrants. The use of more than one disintegrant is obvious and well within the capability of the skilled artisan, absent any new and unexpected results.

Concerning the claimed DISSOLUTION rates, it is maintained that in view of El-Rashidy's disclosure, dissolution time is an art-recognized result-effective variable and it would have been obvious and well within the capability of the skilled artisan to optimize it the compositions of El-Rashidy. The Examiner additionally relies on WO '629 which discloses that dissolution time is one of several known physical characteristics of a tablet (page 3, last three lines). The harder a tablet is the more time it takes to dissolve (page 4, first full paragraph). Absent evidence to the contrary, it would be obvious to one of ordinary skill in the art to modify the components of a composition until a desired dissolution time, i.e. "not less than three minutes", is acquired. For example, the lack of a disintegrant would obviously result in a composition that does not dissolve as quickly as it would with a disintegrant.

Finally, the prior art may not specifically disclose anhydrous compositions containing fluoxetine; however, El-Rashidy et al. teaches methods for making fluoxetine containing compositions wherein said compositions are made with dry ingredients. The fact that preferred example contains a dihydrate compound does not negate the fact that the fabrication process of El-Rashidy is a dry fabrication process and that one of ordinary skill in the art would reasonably expect the ultimate fluoxetine compositions to be essentially free of water.

Claim rejections under 35 USC 112, paragraph 2:

Applicant argues that the conditions of the DISSOLUTION TEST are clearly defined in the specification and that the claims must be interpreted in light of the specification.

However, this does not clearly address the point raised by the Examiner. It is not clear whether the conditions required for the DISSOLUTION TEST in the specification at page 18 remain constant or if they may change over a period of time. The scope of the claims remains uncertain because if the conditions of the test change then the scope of the claims change as well. Further clarification is respectfully requested.

Conclusion

Claims 1-37 stand rejected.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM

July 2, 2001

DWAYNE C. JONES
PRIMARY EXAMINER, 1614